The 2015 Oncology Drug Pipeline: Innovation Drives the Race to Cure Cancer

By Dalia Buffery, MA, ABD
Editorial Director, *American Health & Drug Benefits*

"Innovation drives progress," suggests the US Food and Drug Administration (FDA) in its report on the 41 new molecular entities and new biologic pharmaceuticals that were approved in 2014.[1] This perspective is echoed by the FDA's Center for Drug Evaluation and Research (CDER) as the rationale for its support for innovation in the pharmaceutical industry. The CDER states, "The availability of new drugs and biological products often means new treatment options for patients and advances in health care for the American public. For this reason, CDER supports innovation and plays a key role in helping to advance new drug development."[1]

More recently, in a provocative article published in this journal and titled "Breaking the Bank: Three Financing Models for Addressing the Drug Innovation Cost Crisis," Kleinke and McGee argue that drug innovation is key to medical advances, especially in deadly diseases such as cancer: to ensure continuing innovation in drug therapies, what is needed is not to halt funding innovation but rather to find a new way to pay for drugs. "Innovative new treatments designed to address serious diseases in targeted patient populations represent the future of medicine. Traditional payment methodologies need to change to keep pace with medical innovation," Kleinke and McGee propose, offering 3 models for consideration that will help pay for drugs in a novel way and allow drug innovation to continue in its path.[2]

Reflecting on oncology drugs in its 2014 report, the IMS Institute for Healthcare Informatics (henceforth, IMS) highlighted innovation as a key feature in the oncology pipeline. According to that report, "Developers have brought innovation across cancer types and therapeutic approaches, including preventive vaccines. Pharmaceutical company investments remain high and cancer therapies account for more than 30% of all preclinical and phase 1 clinical development, with 21 new molecular entities being launched and reaching patients in the last two years alone. These new medicines have increased the complexity of treating cancer, leading to more combination therapies and additional lines of therapy."[3]

The Financial Challenge of Innovation

Innovation indeed remains particularly evident in the oncology arena, where exciting new medications have been entering the market at an accelerated pace since early 2014 and through the first half 2015, with many more drugs currently in various phases of development. But innovation comes with a cost, and the cost of cancer drugs continues to be a significant hurdle for patients and for payers.

Advising that innovation in oncology will continue to lead the way in the pipeline in its last year's report, the IMS predicted that "the surge in cancer drug innovation over recent years will continue to contribute to global spending on all oncology drugs, reaching about $100 billion in 2018."[3] This prediction, alas, was much too timid. One year later, in its latest report released in May 2015, the IMS observes that that $100 billion threshold was already reached in 2014, a full 4 years ahead of its prediction 1 year earlier.

Explaining this accelerated rate, the IMS noted, "The landscape is shifting rapidly, bringing new complexity to oncologists, payers and governments….Earlier diagnosis, longer treatment duration and increased effectiveness of drug therapies are contributing to rising levels of spending on medicines for cancer care. Total global spending on such medicines reached the $100 billion threshold in 2014, even as their share of total medicine spending increased only modestly."[4]

Yet this escalation in global spending on oncology drugs represents a lower rate of growth in the United States. According to the IMS, "Global spending on oncology medicines…increased 10.3% in 2014 and reached $100 billion, up from $75 billion five years earlier. The compound average growth rate over the past five years was 6.5% globally on a constant exchange rate basis, though only 5.3% in the U.S."[4]

The growing costs to a large extent reflect the high cost of targeted therapies, which dominate the oncology pipeline. Last year, the IMS report noted, "The high number of new targeted therapies launched and available for cancer patients has also escalated payer scrutiny of

Table 1 Cancer Drugs Approved by Mid-May 2015

Drug trade name (generic)	Manufacturer	Indication/therapeutic class/route	Approval date/ comment
Imbruvica (ibrutinib)	Pharmacyclics	For Waldenström's macroglobulinemia; Bruton's tyrosine kinase inhibitor; oral	*New indication*: 1/29/15
Ibrance (palbociclib)	Pfizer	In combination with letrozole for postmenopausal women with estrogen receptor–positive, human EGFR 2–negative advanced breast cancer; cyclin-dependent kinase 4 and 6 inhibitor; oral	2/3/15 (accelerated approval)
Lenvima (lenvatinib)	Eisai	For locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer; receptor tyrosine kinase; oral	2/13/15
Farydak (panobinostat)	Novartis	In combination with bortezomib and dexamethasone for patients with multiple myeloma who have received at least 2 previous regimens, including bortezomib and an immunomodulatory agent; histone deacetylase inhibitor; oral	2/23/15 (accelerated approval)
Opdivo (nivolumab)	Bristol-Myers Squibb	For metastatic squamous NSCLC that has progressed with or after platinum-based chemotherapy; PD-1–blocking antibody; IV	*New indication*: 3/4/15
Zarxio (filgrastim-sndz)	Sandoz	First biosimilar to Neupogen approved for all the indications for which Neupogen is approved; leukocyte growth factor; subcutaneous/IV	3/6/15
Unituxin (dinutuximab)	United Therapeutics	In combination with granulocyte-macrophage colony-stimulating factor, IL-2, and 13-cis-retinoic acid, for pediatric patients at high risk for neuroblastoma who achieve a partial response or more to first-line multi-agent, multimodality therapy; chimeric monoclonal antibody; IV	3/10/15
Cyramza (ramucirumab)	Eli Lilly	In combination with FOLFIRI for metastatic colorectal cancer that has progressed with first-line bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing regimens; human VEGF receptor 2 antagonist; IV	*New indication*: 4/24/15

EGFR indicates epidermal growth factor receptor; IL, interleukin; IV, intravenous; NSCLC, non–small-cell lung cancer; PD-1, programmed cell death receptor-1; VEGF, vascular endothelial growth factor.

their value relative to their incremental benefits compared to existing treatments. The average cost per month of branded oncology drug…is now about $10,000, up from an average of $5,000 a decade ago."[3] And in its most recent report, the IMS observes, "Targeted therapies now account for almost 50% of total spending and they have been growing at a compound average growth rate of 14.6% over the past five years."[4]

That this high cost of cancer drugs presents a continuing challenge for patients with cancer as well as for payers is not really news; the real issue, as Kleinke and McGee suggest, is how to pay for these drugs in a way that will sustain innovation and improve patient outcomes.[2]

Still, neither the cost nor the slowing rate of growth of cancer drugs has trumped the prominent place of oncology in the pipeline. Despite the reduction in cancer-related death rate, the 2015 annual report of the American Cancer Society indicates that cancer remains the second most common cause of death in the United States, accounting for approximately 1 in 4 deaths, and the total number of cancer cases is growing.[5] In 2015, an estimated 1,658,370 new cases of patients with cancer were projected to be diagnosed in the United States, with an estimated 589,430 deaths,[5] potentially because of the aging of the US population and other demographic trends.

Fast Pace of Cancer Drug Approvals Continues into 2015

By mid-May 2015, 4 new molecular entities or new biologics have already received FDA approval for various tumor types, as well as 2 new indications for drugs that were initially approved by the FDA ≤1 year earlier, as listed in **Table 1**. Of these, 2 approvals were for rare diseases with few treatment options.

One of these new approvals came on the heels of the other. On January 29, 2015, ibrutinib (Imbruvica) was the first cancer drug to receive a new indication this year, representing the first-ever medication to receive FDA approval for Waldenström's macroglobulinemia, a rare disease with few treatment options. On February 3, a new tyrosine kinase inhibitor (TKI), palbociclib (Ibrance), was approved for metastatic breast cancer.

On February 13, lenvatinib (Lenvima) became the newest TKI option for differentiated thyroid cancer, another rare disease. On February 17, lenalidomide (Revlimid) received a new indication for the first-line treatment of patients with multiple myeloma. On February 23, panobinostat (Farydak) became the first-ever histone deacetylase (HDAC) inhibitor to receive FDA approval, also for multiple myeloma.

On March 4, another immunotherapy, the first programmed cell death (PD)-1–blocking antibody, nivolumab (Opdivo), was approved by the FDA for the treatment of patients with metastatic squamous non–small-cell lung cancer (NSCLC).

This is a breathtaking list of new anticancer therapies, with promising outcomes demonstrated in early-stage clinical trials, and with many of the drugs receiving accelerated or priority regulatory reviews to facilitate early access to patients who may benefit from these promising therapies. It may be safe to presume that many of the cancer drugs approved last year will continue to receive second or third indications, or even more, and some will be further approved to facilitate enhanced outcomes within a combination regimen.

Of course, more new cancer drugs are expected to be approved in 2015. Of the 771 cancer drugs currently in development,[6] several drugs are farther along in the process and are expected to be reviewed by the FDA between now and the end of 2015. These drugs potentially are:

- Trabectedin (Yondelis), for chemotherapy-experienced soft-tissue sarcoma, is scheduled to be reviewed by the FDA for approval in July 2015
- Cobimetinib, for melanoma, is scheduled for approval in August 2015
- Gefitinib (Iressa), for first-line advanced or metastatic NSCLC with *EGFR* mutation; approval expected in September 2015
- Sonidegib, for advanced basal-cell carcinoma, with approval expected in September 2015
- Talimogene laherparepvec (T-VEC), for regionally or distally metastatic melanoma, is scheduled for approval in October
- Necitumumab, for the first-line treatment of squamous NSCLC, with a scheduled date of December 2015
- Trifluridine and tipiracil, for third-line therapy of refractory metastatic colorectal cancer, with approval expected by the end of the year.

Oncology Drugs Still a Pipeline Priority

According to the Pharmaceutical Research and Manufacturers of America (PhRMA), 771 new drugs and vaccines are in development by US companies; these agents are currently in clinical trials or have been submitted to the FDA for review.[6] According to PhRMA, of the 771 drugs and vaccines currently in the pipeline[6]:

- 98 are being developed for lung cancer
- 87 for leukemia
- 78 for lymphoma
- 73 for breast cancer
- 56 for skin cancer
- 48 for ovarian cancer.

Overall, 3137 clinical trials for cancer drugs are being conducted in the United States. Of these, 1313 are ongoing and are no longer enrolling new patients.[6] Again, an impressive list of therapies, some with new mechanisms of action that may bring significant changes to cancer care.

Certain trends seen in the FDA approvals in 2014 appear to be continuing in 2015. Of the 41 new molecular entities and new biologics approved last year, 9 were for cancer drugs, including 5 new molecular entities and 4 new biologics. Moreover, several of the new drugs received a second indication in 2014 soon after their initial approval, with some receiving 2 or 3 new indications in succession within a few months. If the first half of 2015 is any indication, this approval trend may linger into 2016 and beyond, with increasing numbers of cancer drugs introducing new mechanisms of action, first-in-class options, or new options for rare cancers.

Several tumor types have attracted significant attention among pharmaceutical developers in recent years, resulting in a concentration of new therapies in the pipeline for specific cancers. Among the categories currently leading the race for FDA approval of new cancer therapies are melanoma, breast cancer, and lung cancer (**Table 2**) and hematologic malignancies (**Table 3**). In addition, several important emerging drugs are in a variety of other tumor types as shown in **Table 4**.

All these drugs are currently in late stages of development, and many drug manufacturers have already submitted New Drug Applications to the FDA for these

Table 2 Promising Late-Phase Drugs for Melanoma, Breast, and Lung Cancers

Drug trade name (generic)	Manufacturer	Expected indication/therapeutic class/route	Development stage/comments (expected approval)
Melanoma			
Talimogene laherparepvec (T-VEC)	Amgen	For metastatic melanoma that is not resectable; oncolytic immunotherapy; intralesional injection	NDA submitted PDUFA: 7/28/15 Submitted to EMA: 9/2014
Cobimetinib (GDC-0973)	Genentech/ Exelixis	For advanced melanoma with *BRAF* V600 mutation; a MEK inhibitor for use in combination with vemurafenib (Zelboraf), a BRAF inhibitor; oral	NDA: priority review PDUFA: 8/11/15
Binimetinib	Array BioPharma	For metastatic melanoma with *NRAS* mutation; MEK inhibitor; oral	Phase 3 trials Est. NDA: mid-2016
Selumetinib	Array BioPharma	For metastatic uveal melanoma; ATP inhibitor; oral	Phase 3 trials
Breast cancer			
Entinostat	Syndax Pharmaceuticals	In combination with exemestane (Afinitor) for ER-positive metastatic breast cancer; HDAC inhibitor	Phase 3 trials BT: 9/12/13
Veliparib (ABT-888)	AbbVie	PARP inhibitor for advanced *BRCA1* or *BRCA2* breast cancer, in combination with chemotherapy; oral	Phase 3 trials
Neratinib	Puma Biotechnology	For early-/late-stage HER2-positive breast cancer; TKI; oral	Phase 3 trials
Lung cancer			
Necitumumab (IMC-11F8)	Eli Lilly	For advanced squamous NSCLC (in combination with gemcitabine plus cisplatin); recombinant human anti-EGFR immunoglobulin G1 monoclonal antibody	Est. approval 12/2015 FDA panel to discuss NDA: 7/9/15
Iressa (gefitinib)	AstraZeneca	For first-line monotherapy of NSCLC with *EGFR* mutation; TKI; oral	NDA: 12/2/14 Est. approval 9/2015
Rociletinib (CO-1686)	Clovis Oncology	For NSCLC with the *EGFR T790M* mutation after progression with anti-EGFR therapy; EGFR inhibitor TKI; oral	BT: 5/19/14 Est. NDA: mid-2015
Atezolizumab (MPDL3280A)	Genentech	For patients with PD-1–positive NSCLC; PD-1–blocking immunotherapy	BT: 2/1/15 Phase 3 trials BT for metastatic bladder cancer: 2014
Tafinlar (dabrafenib)	GlaxoSmithKline	For metastatic NSCLC with *BRAF* V600E mutation; a kinase inhibitor; oral	BT for NSCLC: 1/13/14 Phase 2 trials FDA approved for metastatic melanoma
Alectinib	Roche	For *ALK*-positive NSCLC that progressed with crizotinib; second-generation ALK inhibitor; oral	BT: 6/2013 Phase 2 trials Approved in Japan: 7/7/14
Brigatinib (AP26113)	ARIAD Pharmaceuticals	For *ALK*-positive metastatic NSCLC resistant to crizotinib; a dual ALK/EGFR inhibitor; oral	BT: 10/2/14 NDA: mid-2016
AZD-9291	AstraZeneca	For patients with advanced NSCLC with *EGFR* mutation resistant to EGFR TKI therapy (ie, Iressa); EGFR inhibitor	Phase 2 trials: promising results Est. approval 2/2016
Patritumab	Daiichi Sankyo	Human anti-HER3 antibody for the treatment of NSCLC; oral	Phase 2 trials

ATP indicates adenosine triphosphate; BT, breakthrough therapy; EGFR, epidermal growth factor receptor; EMA, European Medicines Agency; ER, estrogen receptor; Est., estimated; FDA, US Food and Drug Administration; HDAC, histone deacetylase; NDA, New Drug Application; NSCLC, non–small-cell lung cancer; PARP, poly (ADP-ribose) polymerase; PD-1, programmed cell death receptor-1; PDUFA, Prescription Drug User Fee Act; TKI, tyrosine kinase inhibitor.

Table 3 Promising Late-Phase Drugs for Hematologic Malignancies

Drug trade name (generic)	Manufacturer	Expected indication/therapeutic class/route	Development stage/comments (expected approval)
Daratumumab	Janssen Biotech	For relapsed/refractory multiple myeloma; anti-CD38 monoclonal antibody (immunotherapy); IV	BT: 5/1/13 Phase 3 trials
Ixazomib (MLN9708)	Takeda Oncology	For relapsed/refractory multiple myeloma (systemic light-chain amyloidosis); proteasome inhibitor; oral	BT: 1/12/14 Phase 3 trials
Elotuzumab	Bristol-Myers Squibb	In combination with lenalidomide and dexamethasone for patients with multiple myeloma who have received ≥1 previous therapies; humanized immunoglobulin G1 monoclonal antibody; IV	BT: 5/19/14 Phase 3 trials
Volasertib	Boehringer Ingelheim	For patients aged ≥65 years with previously untreated AML who are ineligible for intensive remission induction therapy; PLK inhibitor; IV	BT: 9/17/13 Phase 2 trials Orphan drug: 5/13/14
CTL019	Novartis	For relapsed/refractory ALL in pediatric or adult patients; CAR T-cell therapy; IV	BT: 7/7/14 Phase 1/2 trials
JCAR015	Juno Therapeutics	For relapsed/refractory B-cell ALL; CAR T-cell therapy; IV	BT: 11/24/14 Phase 1/2 trials Orphan drug: 11/18/14
Venetoclax (ABT-199/ RG7601)	AbbVie/Roche	Oral, selective B-cell lymphoma 2 inhibitor, in combination with chemotherapy, for relapsed/refractory CLL	BT: 5/6/15 Phase 3 trials
Pracinostat	MEI Pharma	Oral HDAC inhibitor for myelodysplastic syndrome	Phase 2/3 trials
Vosaroxin	Sunesis Pharmaceuticals	First-in-class quinolone derivative for relapsed/refractory AML; IV	Phase 3 trials
Quizartinib	Ambit Biosciences	Treatment of newly diagnosed patients and patients with relapsed or refractory FLT3-ITD–positive and FLT3-ITD–negative AML; tyrosine kinase inhibitor; oral	Phase 3 trials

ALL indicates acute lymphoblastic leukemia; AML, acute myeloid leukemia; BT, breakthrough therapy; CAR, chimeric antibody receptor; CLL, chronic lymphocytic leukemia; HDAC, histone deacetylase; IV, intravenous; PLK, polo-like kinase.

agents, with an overall estimated approval date anticipated within the next 1 to 2 years.

Breakthrough Therapy Designation Increasing in Oncology

As shown in Table 2 through Table 4, the list of cancer drugs in the pipeline that have already received a breakthrough therapy designation is extensive. A few medications received the designation based on early results from phase 1 or phase 2 clinical trials. According to the FDA, the expressed goal of a breakthrough therapy designation is to support the expedited development process of a drug that has shown significant benefits over therapies that are currently available to patients with a serious or life-threatening disease, such as cancer, and to facilitate the expedited approval of the drug to allow more patients to benefit from such promising therapies.[7]

Therefore, drugs that have received a breakthrough therapy designation are usually reviewed by the FDA for final approval under its priority review and/or accelerated review program, which facilitates the expedited processing of the FDA's review of drugs that treat serious conditions with evidence indicating that their approval would provide significant improvement in safety or effectiveness over current treatment options. As was seen in the past year, the FDA may expedite the approval of therapies that received breakthrough designation a few months ahead of their scheduled approval to allow patients to benefit from these promising therapies as soon as possible.

Abundance of Immunotherapies

Much of the excitement today in cancer drug development involves immunotherapies, which have the potential to bring significant improvements in outcomes, prolonged survival, and progression-free survival, as well as reduced side effects. Many of the drugs in late stages of development or those that have received a breakthrough therapy designation are different types of immunotherapy, which come in various forms and a variety of mechanisms of action, and make up a large proportion of the current pipeline of new therapies coming to market.

Oncology continues to dominate the specialty drug pipeline, with recently introduced immunotherapies representing a variety of mechanisms of action, including the PD-1 antibodies; several anti-CD monoclonal antibodies; new HDAC inhibitors; novel agents targeting different proteins and mutations; new TKIs; and other multikinase inhibitors.

Therefore, despite the rising costs of cancer therapies, there is palpable excitement among those involved in cancer research, with a renewed sense that using human biology to fight cancer-producing cells may eventually move cancer from a death sentence and into the realm of chronic diseases, as in the case of HIV/AIDS. Perhaps not surprising, and similar to the case of HIV/AIDS, therapies that combine ≥2 drugs with several mechanisms of action are gaining more attention in cancer drug development. Combination therapies may indeed be the way of the future for cancer care, with the FDA continuing to approve new combination regimens that improve outcomes and prolong patients' lives.

But challenges remain with immunotherapies. Elaborating on the growing understanding of the role of immunotherapies in cancer care, Alise Reicin, Vice President of Clinical Research, Merck & Co, said, "We think the immune system does recognize cancer, and there is probably something called immune-editing going on, where the immune system finds the cancer and begins the process of trying to kill the tumor. But we're learning that tumors have developed ways to cloak themselves and deactivate the immune system. Tumors start to express a protein PD-L1 or PD-L2. These proteins interact with the protein on the T-cells, and they are

Table 4 Promising Late-Phase Drugs for Various Patient Populations and Tumor Types

Drug trade name (generic)	Manufacturer	Expected indication/therapeutic class/route	Development stage/comments (expected approval)
Rolapitant	Tesaro	For the prevention of chemotherapy-induced nausea and vomiting; selective NK-1 receptor agonist; oral	NDA: 9/2014 Est. PDUFA: 9/5/15 IV formulation in phase 3 trials
Yondelis (trabectedin)	Janssen Pharmaceuticals	For advanced soft-tissue sarcoma, including liposarcoma and leiomyosarcoma; multimodal therapy; IV infusion	NDA: 11/25/14 Priority review: 2/3/15 Est. PDUFA: 11/24/15
TAS-102 (trifluridine + tipiracil hydrochloride)	Taiho Oncology	For third- or fourth-line treatment of refractory metastatic colorectal cancer; combination of antineoplastic nucleoside analog and a hydrochloride	NDA: 2/23/15 PDUFA: 12/19/15
Rindopepimut	Celldex Therapeutics	Immunotherapy for EGFR*vIII*-positive glioblastoma; intradermal	BT for glioblastoma: 1/23/15 Phase 3 trials
MM-398 (irinotecan liposome)	Merrimack Pharmaceuticals	For second-line treatment of metastatic pancreatic cancer; nanotherapeutic derivative of irinotecan; IV	NDA: 4/27/15 Fast track: 11/19/14
Sonidegib (LDE225)	Novartis	For advanced basal-cell carcinoma; selective smoothened inhibitor; oral	NDA: 10/2014 Est. approval: 9/2015
PLX3397	Plexxikon	Recurrent glioblastoma; also in combination with pembrolizumab for advanced melanoma and multiple other solid tumors; tyrosine kinase inhibitor; oral	Phase 2 trials
Tivantinib	ArQule	Treatment of c-MET diagnostic-high inoperable hepatocellular carcinoma treated with 1 previous sorafenib therapy; c-MET inhibitor; oral	Phase 3 trials
Niraparib	Tesaro	For ovarian cancer; PARP inhibitor; oral	Phase 3 trials
Tasquinimod	Active Biotech Research	For castration-resistant prostate cancer; allosteric modulator of HDAC4; oral	Phase 3 trials
Algenpantucel-L	NewLink Genetics	Immunotherapy vaccine for resectable or locally advanced unresectable pancreatic cancer; intradermal injection	Phase 3 trials

BT indicates breakthrough therapy; EGFR, epidermal growth factor receptor; Est., estimated; HDAC, histone deacetylase; IV, intravenous; NDA, New Drug Application (submitted); NK, neurokinin; PARP, poly (ADP-ribose) polymerase; PDUFA, Prescription Drug User Fee Act.

able to deactivate the T-cells so that it no longer recognizes or kills the tumor."[8]

It may, therefore, take some time before the full potential for harnessing the various mechanisms of immunotherapy to kill cancer cells is fully realized and could be successfully translated into cure. Nevertheless, great progress can be seen in the oncology pipeline and in new therapies approved by the FDA for multiple indications in great succession. Immunotherapies against cancer are helping to chart new ways to tame cancer cells and change the outlook for patients.

A true collaboration among government, drug manufacturers, payers, employers, and patients is needed to advance the discussion and bring new solutions to the table. Everyone has a stake in ensuring that patients have access to life-saving drugs, not only drug manufacturers.

Oncology Leading the Biosimilars Buzz

It is perhaps not surprising that the first-ever biosimilar to receive FDA approval (in March 2015) was a cancer drug, Zarxio (filgrastim-sndz), a biosimilar of the original drug Neupogen. What this means to curbing the costs of cancer care remains to be seen, but this approval has finally opened the way for biosimilar entry into the United States, trailing by several years behind Europe.

Several oncology biosimilars are currently in the pipeline and are expected to receive FDA approval in 2015, including:

- Neupeg (pegfilgrastim), a biosimilar to Neulasta, is expected to be approved in August or September of this year
- Grastofil, a second biosimilar to Neupogen, is expected to be approved in October
- Retacrit (epoetin alfa), a biosimilar to Epogen and to Procrit, could be approved later in 2015.

This is likely just the beginning.

Conclusion

With all the excitement and continuing innovation in oncology drugs in the pipeline, and with the new FDA approvals in recent months, serious challenges remain in the oncology pipeline. To sustain innovation, the US healthcare industry must find a way to pay for targeted cancer drugs that have the potential to change the face of this deadly disease, which is to a large degree not related to lifestyle choices. But how to do so remains a major challenge to all healthcare stakeholders, not just patients and payers.

Furthermore, whether the new biosimilars coming soon to market can help in terms of cost containment and expanded access to care is unclear at this point. Even if the anticipated 20% reduction in cost is materialized, this will not be sufficient to change cancer care in any real sense. A true collaboration among government, drug manufacturers, payers, employers, and patients is needed to advance the discussion and bring new solutions to the table. Everyone has a stake in ensuring that patients have access to life-saving drugs, not only drug manufacturers.

For now, despite ongoing and serious concerns over the increasing costs of cancer drugs, new scientific discoveries and new milestones reached with novel drug therapies will likely continue to fuel innovation in oncology drug development, and may eventually chart a way for a new payment system that will ensure continuing innovation and continued improvement in outcomes. This, in turn, will benefit everyone's ultimate goal of transforming cancer from a deadly disease into the chronic disease arena, and potentially even finding a cure for cancer. What only a few years ago seemed an impossible dream no longer appears so, with some cancers already reaching a chronic disease status and cure for many patients. ■

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